

## **REMARKS**

In the Office Action mailed July 25, 2007, the Examiner rejected claims 33-35, 52, and 53 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,261,874 to Castle ("Castle") in view of U.S. Patent No. 5,588,959 to Ahmad et al. ("Ahmad").

By this Reply, Applicant has amended claims 52 and 54, has cancelled claims 33-51 and 53, and has added new claims 65-80. Claims 36-48 and 54-56 were previously withdrawn by the Examiner, however, as amended, claims 54-56 are directed to the same invention that is recited in amended claim 52. No new matter has been added by this Reply.

Claim 52 has been amended to recited, among other things, a "non-invasive measuring device comprising . . . a temperature sensor . . . generating a first signal indicative of a first blood temperature of the blood flowing in said [arterial branch] line, said temperature sensor having an electromagnetic radiation intensity measuring device, and said line comprising a connecting portion of discoid shape facing said measuring device, said connecting portion being permeable to electromagnetic radiation in a first wave band, said first signal corresponding to an intensity of said electromagnetic radiation in said first wave band, a temperature regulating device for regulating the blood temperature in the extracorporeal blood circuit, said device being connected to a portion of the venous branch downstream from said blood treatment element, and a control unit connected to the temperature regulating device and configured to regulate a blood temperature in the extracorporeal blood circuit as a function of the first blood temperature and a reference temperature." Support for the

amendments to claim 52, as well as new claims 65-80, can be found for example, in the specification at page 4, line 28 - page 8, line 32:

Applicant respectfully traverses the Examiner's rejection of claims 33-35, 52, and 53 under 35 U.S.C. § 103(a) as being unpatentable over Castle in view of Ahmad. Castle and Ahmad do not disclose each and every limitation of amended claim 52, nor would one skilled in the art have been able to achieve the invention recited in amended claim 52 based on these references. The Examiner contends that "Castle describes an extra-corporeal blood access sensing, and radiation method and apparatus [that] comprises a line 14 for taking blood from a patient, a pump 18, and inlet 16 to return blood to a patient with sensor 57, a temperature sensor 19 connected to the line, a device 3 for measuring the intensity of the radiation, [and] a connecting portion 4 (co. 5, line 68 through col. 6, line 5)." (Office Action at 3.) The Examiner concedes that "Castle does not specifically disclose first and second signals, however, Castle does teach a means for controlling the temperature." (Office Action at 4.) The Examiner further contends, however, that "Ahmad teaches a temperature control means for the benefit of controlling and/or changing the temperature of the blood returning to the patient (Ahmad col. 5, lines 20-30)" and thus asserts that it would have been obvious "to modify the invention of Castle with a temperature control means for the benefits taught in Ahmad." (Id.) Applicant disagrees.

Applicant submits that Castle discloses that "blood is thus radiated to treat a component of the blood with certain radiation, to heat the blood, to change to blood or parts thereof, to sense and analyze the blood to sense something in contact with the blood or blood stream with SONAR via audio, ultrasonic, or radio-frequency, or to

radiate some foreign organism or material in the blood.” (Col. 3, lines 49-56.)

Moreover, Castle discloses that the “access port(s) and access window(s) are located, configured and sized appropriately to facilitate the desired application of energy or radiation to the blood, its constituents, its interfaces or things therein.” (Col. 3, lines 56-59.) Contrary to the Examiner’s contention, however, Castle does not teach a means for controlling temperature, nor does Castle describe “a temperature sensor 19” or a “device 3 for measuring the intensity of the radiation” as the Examiner contends on page 3 of the Office Action. In fact, there is no discussion of sensing or measuring temperature anywhere in Castle. Moreover, reference numerals 19 and 3 are not used anywhere in Castle, thus the Examiner’s citation of these elements in Castle appear to be in error. Accordingly, Castle does not disclose “a temperature sensor connected to said [arterial branch] line and generating a first signal indicative of a first blood temperature of the blood flowing in said line, said temperature sensor having an electromagnetic radiation intensity measuring device, and said line having a connecting portion of discoid shape facing said electromagnetic radiation intensity measuring device, said connecting portion being permeable to electromagnetic radiation in a first wave band, said first signal corresponding to an intensity of said electromagnetic radiation in said first wave band” (emphasis added), as recited in amended claim 52.

Nor does Castle disclose “a temperature regulating device for regulating the blood temperature in the extracorporeal blood circuit, said device being connected to a portion of the venous branch downstream from said blood treatment element” or “a control unit connected to the temperature regulating device and configured to regulate a blood temperature in the extracorporeal blood circuit as a function of the first blood

temperature and a reference temperature” (emphasis added), as recited in amended claim 52. In fact, as discussed above, Castle does not disclose any means or method for sensing or regulating blood temperature.

Applicant submits that Ahmad discloses “a method for rapidly and inexpensively determining the amount of recirculation in a patient undergoing a dialysis treatment comprising measuring temperature of an arterial limb and a venous limb of a dialysis access.” (Col. 2, lines 38-42.) Ahmad further discloses that the “amount of recirculation will be proportional to the temperature change at the arterial limb” (col. 2, lines 49-50) and that “temperature measurements are made by means of any device that can measure temperature of blood in a tube or in an access device, directly or indirectly, such as a thermometer, a liquid crystal display, infra-red display, thermistor, or infrared light.” (Col. 2, lines 55-60.) Ahmad also discloses a method for analyzing how blood temperature in the arterial line ( $t_2$ ) changes when either the dialysate temperature ( $t_1$ ) or the recirculation rate are changed to show the relation between temperature in the arterial branch and the degree of recirculation. Ahmad does not, however, disclose “temperature sensor having an electromagnetic radiation intensity measuring device, and said [arterial] line having a connecting portion of discoid shape facing said electromagnetic radiation intensity measuring device, said connecting portion being permeable to electromagnetic radiation in a first wave band, said first signal corresponding to an intensity of said electromagnetic radiation in said first wave band” (emphasis added), as recited in amended claim 52.

Ahmad also does not disclose “a temperature regulating device for regulating the blood temperature in the extracorporeal blood circuit, said device being connected to a

portion of the venous branch downstream from said blood treatment element" (emphasis added), as recited in amended claim 52. Ahmad discloses a "means for measuring temperature in a venous limb" (col. 5, line 66), however, it does not disclose a means for regulating temperature in the venous limb. In addition, Ahmad fails to disclose "a control unit connected to the temperature regulating device and configured to regulate a blood temperature in the extracorporeal blood circuit as a function of the first blood temperature and a reference temperature" (emphasis added), as recited in amended claim 52. As discussed above, Ahmad does not disclose a temperature regulating device connected to the venous branch, and thus, does not disclose a control unit connected to such a temperature regulating device. Moreover, the only method for regulating temperature disclosed in Ahmad relates to determining the amount of circulation, thus Ahmad does not regulate temperature in the venous branch as a function of a reference temperature and a blood temperature measured in the arterial branch, as recited in amended claim 52.

Therefore, for at least these reasons, Ahmad fails to cure the above-mentioned deficiencies of Castle with regards to amended claim 52. Thus, amended claim 52 is allowable over Castle in view of Ahmad. Accordingly, claim 53 is allowable at least due to its dependence from allowable amended claim 52 and due to its additional recitations of novel subject matter.

Applicant points out that the Examiner did not reject claims 54-67 under 35 U.S.C. § 103(a) as being unpatentable over Castle in view of Ahmad. In fact, the Office Action does not provide any rejection of claims 54-67. Accordingly, claims 54-67 should be allowed at least due to the lack of a standing rejection. Nevertheless, Applicant

submits that claims 54-67 are allowable at least due to their dependence from allowable amended claim 52 and due to their additional recitations of novel subject matter.

Further, new claims 65-80 all depend from allowable amended claim 52, either directly or indirectly. Accordingly, new claims 65-80 are allowable at least due to their dependence from allowable amended claim 52 and due to their additional recitations of novel subject matter.

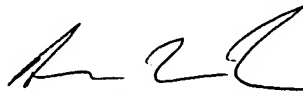
In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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